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| 10/672,239  | 09/25/2003  | Daniel Darst         | 40070-0360                       | 8709             |
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| HELLER EHRMAN LLP<br>4350 LA JOLLA VILLAGE DRIVE #700<br>7TH FLOOR<br>SAN DIEGO, CA 92122 |             |                      | EXAMINER<br>FLORES SANCHEZ, OMAR |                  |
|   |             |                      | ART UNIT<br>3724                 | PAPER NUMBER     |

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/672,239

Applicant(s)

DARST, DANIEL

Examiner

Omar Flores-Sánchez

Art Unit

3724

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) 10-16, 30-33, 39-41, 45-50 and 60-72 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-38 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 17, 18, 20-29, 42-44, 51-56, 58, 59 and 73-83 is/are rejected.
- 7) ☒ Claim(s) 6, 19 and 57 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/27/04 and 7/11/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Objections*

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 75-82 been renumbered 76-83 (see page 13, where there is two claims 75.

### *Election/Restrictions*

2. Claims 10-16, 30-33, 39-41, 45-50, 60, 61 and 68-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/27/05.

Also, claims 62-67 are withdrawn as being drawn to a nonelected species IV of Fig. 9-10C. Evidence can be found in claim 62, where the "raised region that slides over the blade" is illustrated on Fig. 9.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 3, 5, 7, 8, 73-82 and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaffney et al. (3,517,871).

Gaffney et al. discloses (Fig. 1-9) the invention including:

- a. Claims 1, 73-75, 79, 80 and 81; a base (12 and 42) having a pill cutting surface, a lid (22 and 52) connected to the base (by a hinge 26 and 56), a blade/cutting device (21 and 51); and a retractable blade guard (31, 32, 54, 61, and 62) secured to the base (by a hinge 26 and 56) and engaging/coupled the lid (see Fig. 4 and 8).
- b. Claim 2; a flexible strip of material (col. 2, lines 52-53) that is substantially impermeable to the blade (to the side of the blade see Fig. 4).
- c. Claim 3; a plastic material 54 (see Fig. 7, where the drawing symbol indicate plastic material [see MPEP 608.02]).
- d. Claim 5; a hinge (26 and 56).
- e. Claim 7; the blade guard is retractable in order to cover the blade when the lid is open (see Fig. 4 and 8) and it retracts to expose the blade when the lid is closed (see Fig. 3 and 7).
- f. Claim 8; a pill grip having first and second arms 43 and 44.
- g. Claim 76; the lid includes channels (where the plunger is located and the spring is connected with the lid).
- h. Claims 77 and 82; the channels guide the retractable guard (see Fig. 6 and 7).
- i. Claims 78 and 83; the retractable guard moves linearly (see Fig. 8).

5. Claims 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Lluch (6,449,218 B1).

Lluch discloses (Fig. 1-4) the invention including:

- a. Claim 42; a base 14, a lid 68 connected to the base by one or more hinges (see Fig. 3), the lid having a top side and a bottom side; and a color-coded attachment (see col. 6, lines 5-9) detachably fixed to the top side of the lid.
- b. Claim 43; the specific content of “one color indicates that the container comprises a pill splitter” does not serve to patentably distinguish the claimed invention from the prior art (see MPEP 2112.01(III), *In re Ngai*, 70 USPQ2d 1862 (Fed. Cir. 2004)).

6. Claims 51, 53, 54, 56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaffney et al. (3,517,871).

Gaffney et al. discloses (Fig. 1-9) the invention including a kit comprising:

- a. Claim 51; one or more pills (see Fig. 9), a base (12 and 42) having a pill cutting surface, a lid (22 and 52) connected to the base (by a hinge 26 and 56), a blade (21 and 51); and a retractable blade guard (31, 32, 54, 61, and 62) secured to the base (by a hinge 26 and 56) and engaging the lid (see Fig. 4 and 8).
- b. Claim 53; a flexible strip of material (col. 2, lines 52-53) that is substantially impermeable to the blade (to the side of the blade see Fig. 4).
- c. Claim 54; a plastic material 54 (see Fig. 7, where the drawing symbol indicate plastic material [see MPEP 608.02]).

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- d. Claim 56; a hinge (26 and 56).
- e. Claim 58; a pill grip having first and second arms 43 and 44.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4, 21 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffney et al. (3,517,871) in view of Reitano (6,474,525 B1).

Gaffney et al. discloses the invention substantially as claimed except for a metallic material. However, Reitano teaches the use of a metallic material (see col. 4, lines 3-6) for the purpose of resisting repeated impact forces. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Gaffney et al. by providing the metallic material as taught by Reitano in order to obtain a device that resists repeated impact forces.

9. Claims 9 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffney et al. (3,517,871) in view of Dienst (US 2003/0019900 A1).

Gaffney et al. discloses the invention substantially as claimed except for a second portion that is flexible. However, Dienst teaches the use of a second portion (403 and 405) that is flexible for the purpose of preventing pill slippage. It would have been obvious to one having

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ordinary skill in the art at the time the invention was made to have modified the device of Gaffney et al. by providing the second portion that is flexible as taught by Dienst in order to obtain a device that prevents pill slippage.

10. Claims 17, 18, 20, 22 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffney et al. (3,517,871) in view of Buckley et al. (6,601,746 B2).

Gaffney et al. discloses (Fig. 1-9) the invention substantially as claimed including:

- a. Claim 17; a base (12 and 42) having a pill cutting surface, a lid (22 and 52) coupled to the base (by a hinge 26 and 56), a hinge (26 and 56), a pill grip (43 and 44), a blade (21 and 51) and a retractable blade guard (31, 32, 54, 61, and 62).
- b. Claim 18; a flexible strip of material (col. 2, lines 52-53) that is substantially impermeable to the blade (to the side of the blade see Fig. 4).
- c. Claim 20; a plastic material 54 (see Fig. 7, where the drawing symbol indicate plastic material [see MPEP 608.02]).
- d. Claim 22; the blade guard is retractable in order to cover the blade when the lid is open (see Fig. 4 and 8) and it retracts to expose the blade when the lid is closed (see Fig. 3 and 7).
- j. Claim 28; the pill grip having first and second arms 43 and 44.

Gaffney et al. does not show a pill storage compartment. However, Buckley et al. teaches the use of compartment 31 for the purpose of storing the tablets. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have

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modified the device of Gaffney et al. by providing the compartment as taught by Buckley et al. in order to obtain a device for storage the tablets.

11. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffney et al. (3,517,871) in view of Buckley et al. (6,601,746 B2) as applied to claims 17 and 28 above, and further in view of Reitano (6,474,525 B1).

The modified device of Gaffney et al. discloses the invention substantially as claimed including the first and second walls (the interior walls, where the plunger and the pads slide). Gaffney et al. does not show channels. However, Reitano teaches the use of channels 8 for the purpose of easily guiding the plunger. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Gaffney et al. by providing channels as taught by Reitano in order to obtain a device that easily guides the plunger and the pad.

12. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffney et al. (3,517,871) in view of Buckley et al. (6,601,746 B2) as applied to claim 17 above, and further in view of Bendickson et al. (4,825,552).

Gaffney et al. discloses (Fig. 1-9) the invention substantially as claimed except for finger grips with raised ribs. However, Bendickson et al. teaches the use of finger grips with raised ribs 37 for the purpose of improving the gripping surface. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of



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Gaffney et al. by providing the finger grips with raised ribs as taught by Bendickson et al. in order to obtain a device that improves the gripping surface.

13. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffney et al. (3,517,871) in view of Buckley et al. (6,601,746 B2) and Bendickson et al. (4,825,552) as applied to claims 17 and 28 above, and further in view of Dienst (US 2003/0019900 A1).

The modified device of Gaffney et al. discloses the invention substantially as claimed except for a second portion that is flexible. However, Dienst teaches the use of a second portion (403 and 405) that is flexible for the purpose of preventing pill slippage. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Gaffney et al. by providing the second portion that is flexible as taught by Dienst in order to obtain a device that prevents pill slippage.

14. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lluch (6,449,218 B1) in view of Gaffney et al. (3,517,871).

Lluch discloses the invention substantially as claimed including a base 34, a lid 32 connected to the base and a blade 48. Lluch does not show a retractable blade guard. However, Gaffney et al. teaches the use of a retractable blade guard (31, 32, 54, 61, and 62) secured to the base (by a hinge 26 and 56) and engaging the lid (see Fig. 4 and 8) for the purpose of protecting the projecting portion of the blade. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Lluch by providing the

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retractable blade guard as taught by Gaffney et al. in order to obtain a device that protects the projecting portion of the blade.

15. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffney et al. (3,517,871) in view of Stevens (3,815,802).

Gaffney et al. discloses (Fig. 1-9) the invention substantially as claimed except for instructions. However, Stevens teaches the use of instructions for the purpose of instructing the patient how to use the tool. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Gaffney et al. by providing the instructions as taught by Stevens in order to obtain a device that shows the patient how to use the tool. Also, the specific content of those instructions does not serve to patentably distinguish the claimed invention from the prior art (see MPEP 2112.01(III), *In re Ngai*, 70 USPQ2d 1862 (Fed. Cir. 2004)).

***Allowable Subject Matter***

16. Claims 34-38 are allowed

17. Claims 6, 19, 34 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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18. The following is an examiner's statement of reasons for allowance: The claim is allowable because the prior art fails to teach the lid having a cam 94 and the blade guard is threaded 18 over the cam as set forth in claims 6, 19, 34 and 57.

Gaffney et al. teaches the blade guard is mounted over the inside surface 22 or plunger 54 without the use of threaded device (see Fig. 2 and 5). Also, the inside surface 22 and plunger 54 can't function or replaced by a cam, because their function are to support the blade guard, rather than transform linear motion into a rotary motion or vise versa. For those reasons, Gaffney et al. fails to teach the lid having a cam and the blade guard is threaded over the cam as set forth in claims 6, 19, 34 and 57.

### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stock, Moeller, Lieptz, Scalise et al., Fiocchi, Zellner, Weinstein, Khachatoorian et al. and Eric are cited to show related device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Omar Flores-Sánchez whose telephone number is 571-272-4507. The examiner can normally be reached on 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Allan Shoap can be reached on 571-272-4514. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**Allan N. Shoap**  
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